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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/810,231

03/25/2004

Mary Jo. A. Toomey

7056 US (1)

9460

55748 7590 06/05/2007
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EXAMINER

CHAPMAN, GINGER T

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,231

Applicant(s)

TOOMEY ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

1. Claims 42-46 are added and claims 8 and 25-41 are canceled by way of Applicants' amendment filed 22 February 2007; claims 1-7, 9-12 and 42-46 are pending in the application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 10-12 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman (US 5,342,328).

2. With regard to claims 1 and 46, as best depicted in Figures 7 and 8, Grossman et al disclose a fluid collection apparatus (fig. 3) comprising: a housing (11) configured for receipt of fluid and having a first surface which defines a needleless first mating portion (15); a holder (16) having a first end and a second end (fig. 4) configured to receive an evacuated tube (30), the first end (17b) defining a second mating portion (40) on an outer surface thereof (43) which is in fluid communication (45) with the evacuated tube (30), the first mating portion (17b) adapted to releasably couple and sealingly engage the second mating portion (40) (c. 4, ll. 25-43) to establish fluid communication therebetween; and a base (13) disposed within the housing, the base being positionable on a support surface to support the holder and the housing in upstanding relationship with respect to the support surface (fig. 2).

With regard to claim 2, as best depicted in Figure 2, Grossman et al disclose the base (13) has a top opening adapted for receiving the housing (15, 11).

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With regard to claim 3, as best depicted in Figure 2, Grossman et al disclose the base (13) is adapted for standing on a surface (c. 3, ll. 8-9).

With regard to claim 4, as best depicted in Figures 2 and 4, Grossman et al disclose the base (13) is configured to enclose holder (16).

With regard to claim 5, Grossman et al disclose the housing (11) has a flange portion (43) extending radially therefrom that engages the base (15).

With regard to claims 6 and 7, Grossman et al disclose at least one rib (19) and a plurality of ribs (19).

With regard to claims 10 and 11, Grossman et al disclose a removable cap (22) adapted to removably enclose an opening of the housing (11) and provides a fluid seal within housing.

Claims 9 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (US 5,342,328).

3. With regard to claim 9, Grossman et al disclose the base (13) includes a plurality of sidewall extensions (13) but does not disclose the sidewall extensions separated by cutout portions. Grossman at c. 3, ll. 8-9 teaches that the sidewall extensions provide a level support base for standing housing on a level surface thus disclosing a desire for means to support and stand the apparatus on a level surface. As seen in Figures 2 and 4, Grossman teaches the sidewall extensions providing a level support base for standing the apparatus comprising its housing on a level surface. After review of the instant specification, in particular at p. 16, ll. 13-21 and the instant Figure 12, disclosing that the cutouts are optional depending on the material used, it is noted that Applicant provides no criticality for the cutout portions. The specification

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contains no disclosure of either the critical nature of the claim limitations nor any unexpected results arising therefrom, and that as such the limitations were arbitrary and therefore obvious. It appears the invention would work equally well with or without the cutout portions as best depicted in the instant figure 12. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the sidewall extensions with cutout portions, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same function as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

4. With regard to claims 42-44, Grossman discloses the claimed invention except for the male and female luer connectors. Grossman, at c. 4, ll. 26-27, teaches the ability of a valve to establish fluid communication between the first and second mating portions thus disclosing a desire for connectors capable of establishing fluid communication. As seen in Figure 7, Grossman teaches a poppet valve mechanism (40) to establish fluid communication between the first mating portion (17b) and the second mating portion (38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the fluid communication connectors comprising either a poppet valve or luer connectors to perform the substantially identical claimed function of establishing fluid communication. In the instant case substitution of equivalent methods requires no express motivation, as long as the prior art recognizes equivalency. *In re Fount* 213 USPQ 532 (CCPA 1982); *In re Siebentritt* 152 USPQ.

Claims 12 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (US 5,342,328) in view of Szeles (EP 1,295,561 A1).

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5. With regard to claim 12, Grossman et al disclose the invention substantially as claimed except for the removable cap includes a finger grip. Szeles, at c. 7 [0039] to c. 8, ll. 1-5 teaches the ability of a removable cap (12, 40) to include mating threads and ridges and protrusions to provide means for the user of the apparatus to attach the cap to the container as described at c. 9, [0043]. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the cap of Grossman including gripping portions as taught by Szeles since Szeles states at c. 3 to c. 4, [0021] that the advantage of forming a cap with this design is that the cap seals the container and at [0043] that the cap can be removed and reapplied by the user of the apparatus.

6. With regard to claim 45, Grossman discloses the claimed invention except for explicitly disclosing the base having a height sufficient to enclose the evacuated tube, Szeles, at [0008], expresses the desire for a container that can safely hold an evacuated tube. As seen in Figure 7, Szeles teaches a base of sufficient height to enclose an evacuated tube (86). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the base of Grossman enclosing the tube as taught by Szeles since it has been held that a change in size involves only routine skill in the art and Szeles states at [0009] that when the tube is placed in the base and the lid is sealed on the container fluid communication is established when the tube is inserted into the base.

Response to Arguments

Applicant's arguments filed 22 February 2007 have been fully considered but they are not persuasive.

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7. Applicant argues the following:

Claim 1 has been amended to recite the limitation that the first mating portion is adapted to releasably couple and sealingly engage the second mating portion to establish fluid communication therebetween, while Applicant interprets Grossman as disclosing that the needle hub (17b) is monolithically formed with the housing and that the needle hub 17b is not releasably coupled to the housing.

8. This argument is not persuasive for the following reasons:

(a). as disclosed with regard to the embodiment depicted in Figure 8 of Grossman, element 17b is the blood collection port which can be releasably and sealingly engage the needle (18) hub of syringe (38), said syringe then performing the function of the second mating portion.

(b). with regard to the limitation of the needle hub being monolithically formed or separably formed, the instant specification discloses at p. 6, ll. 23-24; p. 11, ll. 7-8 and p. 12, ll. 27-28 forming the components monolithically and the locking surfaces may be permanent is disclosed as being a suitable embodiment of the instant claimed invention.

The examiner notes Grossman discloses the invention as claimed, except for (a) Grossman utilizes a poppet valve mechanism (40) while the instant claimed apparatus uses male and female luer connectors, and (b) the location of the prior art needle/needle hub is on the first mating portion while the instant needle/needle hub is located on the second mating portion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571) 272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
05/24/07



TATYANA ZALUKAEVA
SUPERVISORY EXAMINER
